



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6209]

Assessing User Fees Under the Biosimilar User Fee Amendments of 2017; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” This draft guidance concerns FDA’s implementation of the Biosimilar User Fee Amendments of 2017 (BsUFA II) and certain intended changes in policies and procedures surrounding its application.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-D-6209 for “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Beena Alex, Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2185, Silver Spring, MD 20993, 301-796-7900, CDERCollections@fda.hhs.gov; or to Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” This draft guidance concerns the implementation of BsUFA II, including an explanation about the new fee structure and types of fees for which entities are responsible. BsUFA II extends FDA’s authority to collect user fees from fiscal year 2018 to 2022 and introduces a number of technical revisions that affect what fees are collected and how fees are collected. Fees authorized by this legislation help fund the

process for the review of biosimilar biological product applications and have played an important role in expediting the review and approval process.

BsUFA II authorizes biosimilar biological product development program fees (BPD fees), biosimilar biological product application fees, and biosimilar biological product program fees. This draft guidance describes when these fees are incurred and the process by which applicants can submit payments. The draft guidance also provides information on consequences of failing to pay BsUFA II fees and the processes for submitting reconsideration and appeal requests.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on assessing user fees under BsUFA II. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 C.F.R. 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this document, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Assessing User Fees Under the Biosimilar User Fee Amendments of 2017: Draft Guidance for
Industry

OMB Control Number 0910-NEW

This information collection supports "Assessing User Fees Under the Biosimilar User Fee Amendments of 2017: Draft Guidance for Industry." The Federal Food, Drug, and Cosmetic Act as amended by the Biosimilar User Fee Act of 2012 and recently renewed in 2017 (BsUFA II) under the FDA Reauthorization Act of 2017, authorizes FDA to assess and collect user fees from companies that produce biosimilar biological products in conjunction with the review of biosimilar biological product applications. The draft guidance includes processing and policies for the initial and the annual BPD fees; the BPD discontinuation process requirements and BPD reactivation fees; process and policies for biosimilar biological product application fees including exceptions to the application fees and refund of fees; process and policies for the small

business waiver of the biosimilar application fee; and implementation of the biosimilar biological product program fee.

The burdens associated with requesting a small business waiver of BsUFA fees and the associated burdens for new activities as noted in the draft guidance are listed in table 1.

FDA estimates the annual burden of these new collections of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Request for discontinuation from BPD program	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list	5	1	5	.5	2.5
Small business waiver of the BsUFA application fee	1	1	1	16	16
- Reconsiderations	1	1	1	24	24
- Appeals	1	1	1	12	12
Annual Fee Determination Survey	35	1	35	1	35
Annual BsUFA Fees Correspondence	35	1	35	2	70
Total					161.5

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance also refers to previously approved collections of information found in FDA forms developed to support its user fee program. Specifically, the draft guidance refers to Form FDA 3792, Form FDA 3913, and Form FDA 3971, which have been approved under OMB control numbers 0910-0718, 0910-0805, and 0910-0693, respectively. The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 are currently approved under OMB control number 0910-0014; the collections of information regarding new drug applications and biologics license applications are approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,
<https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: November 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-24831 Filed: 11/15/2017 8:45 am; Publication Date: 11/16/2017]